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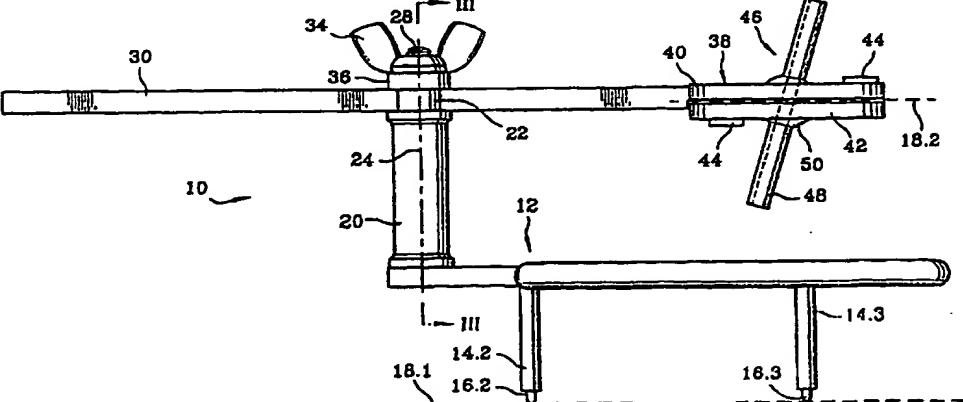
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(71) Applicant (for all designated States except US): IMPLICO B.V. [NL/NL]; Atrium Building, Strawinskyalaan 3127, NL-1007 JB Amsterdam (NL). (72) Inventor; and (75) Inventor/Applicant (for US only): ADAMS, Laurence, Pen-tocost [GB/ZA]; 5 Maryland Avenue, Tokai, Cape Town, Western Cape Province (ZA). (74) Agent: SMULDERS, Th. A.H.J., Vereenigde Octrooibureaux, Nieuwe Parklaan 97, NL-2587 BN The Hague (NL).		
(54) Title: STEREOTACTIC POINTING DEVICE		
		
(57) Abstract		
<p>A surgical guidance device for the precise positioning of a surgical object, comprises a base (12) having three feet (16.1, 16.2 and 16.3) which define a first plane (18.1), a swivel head (38) at the end of a radius arm (30), and a guide (46) for guiding the surgical object, the guide being mounted on the swivel head (38). The radius arm is slidable in its longitudinal direction and pivotally displaceable about a pivot axis (24) which is normal to the plane (18.1). This enables the swivel head (38) to be moved to any position in a plane (18.2) parallel to the plane (18.1). Tightening of a wing nut (34) locks the swivel head in position. There is a ball-and-socket connection between the guide and the swivel head, whereby the swivel head can swivel about a pivot point in any direction with respect to the swivel head, and can be locked in position by means of clamping screws (44).</p>		

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Stereotactic pointing device

THIS INVENTION relates to a surgical guidance device, for the precise positioning of a surgical object such as, for example, a needle, probe, catheter, or the like in a patient. It also relates to a method 5 of guiding a surgical object to a target position in a patient.

According to the invention there is provided a surgical guidance device for the precise positioning of a surgical object, which comprises:

- 10 a base having three feet which define a first plane;
- a swivel head which is constrained for movement in a second plane spaced from and parallel to the first plane;
- 15 a guide for the surgical object, the guide being mounted on the swivel head so that it can swivel with respect to the swivel head in all directions about a pivot point; and
- locking means for locking the swivel head in a 20 selected translational position in the second plane and the guide in a selected angular position with respect to the swivel head.

The swivel head may be mounted on a radius arm, the radius arm may be mounted on the base so as to 25 be pivotally displaceable with respect to the base about a pivot axis normal to the first plane, and the radius arm may be slidably displaceable with respect to the base or the swivel head, whereby the radial distance between the swivel head and pivot axis can be 30 varied.

The guide may comprise a guide tube along which a pin forming the surgical object or having the

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surgical object attached thereto, can slide with little clearance, the tube being connected to the swivel head via a ball-and-socket connection.

The guide tube may have a spherical formation
5 between the ends and on the outside thereof, and the
swivel head may comprise a pair of annular clamping
plates between which the spherical formation is held,
the clamping plates and the spherical formation forming
said ball-and-socket connection, and locking of the
10 guide in a selected angular position with respect to
the swivel head being effected by clamping the clamping
plates together to grip the spherical formation
therebetween.

The surgical guidance device may have, in
15 combination therewith as part of a kit, a phantom which
comprises a plate having an opening therein and, spaced
around the opening, three locating formations whose
positions relative to one another correspond to the
positions of said feet relative to one another, and the
20 phantom further comprising a target block below the
opening, the target block being slid able in three
mutually orthogonal directions along graduated slides.

Further according to the invention there is
provided a method of guiding a surgical object to a
25 target position in a patient, the method comprising:
utilising a guidance device having a base with
three feet which define a first plane, a swivel head
which is constrained for movement in a second plane
spaced from and parallel to the first plane, and a
30 guide for the surgical object, the guide being mounted
on the swivel head so that it can swivel with respect
to the swivel head in all directions about a pivot
point;
applying at least three markers to the body of the

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patient, the positions of the markers relative to one another corresponding to the positions of said feet relative to one another;

5 determining the co-ordinates of the target position and each of the markers, in a three co-ordinate system;

setting up the guidance device by adjusting the translational position of the swivel head in the second plane and adjusting the angular position of the guide
10 with respect to the swivel head;

locking the swivel head and the guide in their adjusted positions;

15 placing the guidance device on the patient so that the feet are in register with the positions of said markers; and

inserting the surgical object into the patient along the guide.

The invention will now be described in more detail, by way of example, with reference to the
20 accompanying drawings.

In the drawings:

Figure 1 is a side view of a surgical guidance device in accordance with the invention;

25 Figure 2 is a plan view of the device;
Figure 3 is a section on III-III in Figures 1 and 2;

Figure 4 is a section on IV-IV in Figure 2, drawn to a larger scale;

30 Figure 5 shows the back of a patient's head, to illustrate one of the procedures in which the guidance device can be used;

Figure 6 illustrates a setting diagram that is produced by a PC-driven printer, for use in setting up the guidance device;

35 Figure 7 is a side view, shown partly in section,

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of an accessory used in setting up the guidance device;
and

Figure 8 is a cut-away pictorial view of a phantom
used to verify the setting of the guidance device.

5 Referring first to Figures 1 to 4, reference
numeral 10 generally indicates a surgical guidance
device comprising a base 12. The base 12 has three
legs 14.1, 14.2, and 14.3, each with a pointed (but not
sharp) foot 16.1, 16.2, and 16.3 respectively. The
10 tips of the feet 16.1 to 16.3 define a first plane
18.1.

Fast with the base 12 there is an upright
post 20. The post 20 is bored to receive a spindle 22
which is rotatable with respect to the base 12 about a
15 pivot axis 24, the pivot axis being normal to the plane
18.1. The spindle 22 has a tapered head 26 at the
lower end thereof, and a threaded portion 28 at the
upper end thereof.

The device 10 further comprises a radius arm
20 30 which is of square cross-section and is slidable in
a slotted opening 32 in the spindle 22. A wing nut 34
engages with the threaded portion 28, and between the
wing nut and the radius arm 30 there is a spacer ring
36. When the wing nut 34 is slightly loose, the radius
25 arm 30 can slide along the slotted opening 32, in the
longitudinal direction of the radius arm, and can pivot
with respect to the base 12 about the pivot axis 24.
When the wing nut 34 is tightened, the radius arm 30 is
30 clamped between the upper face of the post 20 and the
spacer ring 36. This is effective to lock the radius
arm in position, locating it against sliding movement
in its longitudinal direction and against pivotal
movement about the pivot axis 24.

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At one end of the radius arm 30 there is a swivel head 38. The swivel head 38 comprises two annular clamping plates, namely an upper plate 40 and a lower plate 42, which can be clamped together by means 5 of a pair of clamping screws 44. The swivel head 38 carries a guide 46 which consists of a guide tube 48 having, between the ends thereof, a spherical formation 50 on the outside thereof. The clamping plates 40 and 42, in conjunction with the spherical formation 50, 10 form a ball-and-socket connection between the swivel head 38 and the guide 46. When the clamping screws 44 are slightly loose, the guide 46 is able to pivot in all directions about a pivot point which coincides with the centre of the spherical formation 50.

15 The entire device is of stainless steel so that it can readily be sterilized.

The manner in which the device 10 is used, for example, to carry out a biopsy procedure on the brain of a patient will now be described, with 20 reference also to Figures 5 to 8. To carry out this procedure it is necessary to bring the tip of a biopsy needle precisely to a predetermined position in the brain of the patient. The guidance device 10 has been designed to assist the surgeon in achieving this. Many 25 of the steps described below are carried out by assistants outside the operating theatre, so that they do not take up the surgeon's time.

First, a computed tomography (CT) scan is taken of the patient's head. Before taking the CT 30 scan, four adhesive marker discs are placed in position on the patient's head (see Figure 5). The first one, indicated by reference numeral 60, marks the entry point where the surgeon wishes to enter the patient's cranium. The other three marker discs, indicated by

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reference numerals 62.1, 62.2, and 62.3, are placed around the marker disc 60, the spacing between the centres of the marker discs 62.1, 62.2, and 62.3 corresponding to the spacing between the feet 16.1, 5 16.2, and 16.3 respectively. To facilitate the correct positioning of the discs 62.1 to 62.3, a template comprising three legs whose configuration is identical to that of the legs 14.1 to 14.3 may be used. Each of the marker discs 60 and 62.1 to 62.3 has a 2mm opening 10 at the centre thereof. After the marker discs have been placed in position, a 2mm steel ball is placed in each of the 2mm openings, whereupon the CT scan can commence. The steel balls form radio-opaque markers which are readily visible on the CT scan images.

15 The images obtained by the CT scan enable the rectangular co-ordinates (x, y, and z) of any feature shown by the CT scan to be determined. The x and y co-ordinates are determined by moving a cursor on the display screen when displaying a particular CT slice, 20 to the feature in question. The z co-ordinate corresponds to the "table position" of the slice.

A conventional CT scan of the region of interest and consisting of a series of slices is taken, so as to enable the co-ordinates of the point in the 25 patient's brain (ie the target) from where the biopsy is to be taken to be determined. The table on which the patient is supported in the CT scan apparatus is then moved to align one of the steel balls with the plane of the CT scan apparatus and a scan taken in that 30 particular table position. This enables the co-ordinates of the steel ball to be determined. The process is repeated for each of the other steel balls, and then once more for the first ball to verify that no significant movement of the patient's head has taken 35 place between the readings. Once the CT scans have

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been completed the steel balls can be removed.

The co-ordinates of five positions will then be available, ie those of the target, the entry point (corresponding to the centre of the marker disc 60),
5 and the centres of each of the marker discs 62.1, 62.2, and 62.3. With these co-ordinates the guidance device
10 can be set up to guide the biopsy needle precisely to the target.

There are various ways in which the guidance
10 device 10 can be set up. One of these, making use of a suitably programmed PC or lap-top computer linked to a printer, will now be described.

The co-ordinates of each of the various positions are entered into the computer. The computer,
15 making use of the mathematics of three-dimensional transformations and co-ordinate geometry, computes from this data the co-ordinates, in the plane defined by the centres of the marker discs 62.1 to 62.3, of the perpendicular projections on this plane, of the entry
20 point, the target, and the points at which a straight line passing through the entry point and the target position (the entry-point-to-target line) intersects the second plane 18.2. These computed positions, as also the positions of the centres of the marker discs
25 62.1 to 62.3 and the point at which the entry-point-to-target line intersects the plane 18.1, are then plotted by means of the printer on a sheet of paper, to form a setting diagram 64 as illustrated in Figure 6. In the setting diagram the positions of the centres of the
30 marker discs 62.1 to 62.3 are indicated by the numbers 1, 2, and 3 respectively. The point at which the entry-point-to-target line intersects the plane 18.2 is indicated by the letter P, and the point at which the entry point to target line intersects the plane 18.1 by

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the letter D. The setting diagram also indicates the projected positions of the entry point and the target (or tumour), as indicated in the drawing.

The setting diagram is placed on a flat supporting surface and the guidance device 10 is placed on the diagram, with the feet 16.1, 16.2, and 16.3 being in register with the points 1, 2, and 3 respectively. The triangle defined by the feet 16.1, 16.2, and 16.3 is preferably one that is not equilateral, so that only one correct position of the guidance device 10 on the plot is possible. The wing nut 34 and at least one of the clamping screws 44 are slightly loosened. This will enable the swivel head 38 to be moved to any desired position in the plane 18.2, and will also enable the guide 46 to be swivelled in any desired angular position with respect to the swivel head. The guide 46 is aligned with respect to the swivel head 38 so that the centre line of the guide tube 48 is normal to the planes 18.1 and 18.2. To facilitate this, an accessory 66 as illustrated in Figure 7 is provided. The accessory 66 comprises a head 68 whose lower end defines a plane 70, and a pin 72 which extends at right angles to the plane 70. The distance between the tip of the pin 72 and the plane 70 corresponds to the distance between the upper face of the clamping plate 40 and the plane 18.1 when the centre line of the guide tube 48 is normal to the plane 18.1. The pin 72 is receivable with little clearance in the guide tube 48. The pin 72 is inserted into the guide tube 48 and manoeuvred until the plane 70 lies flat against the upper face of the clamping plate 40. When this is the case the centre line of the guide tube 48 is normal to the plane 18.1 and the tip of the pin 72 will touch or almost touch the setting diagram 64. With the wing nut 34 still in a slightly loose condition, the swivel head 38 is moved in the plane

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18.2 until the tip of the pin 72 is in register with the point P on the setting diagram. The wing nut 34 is now tightened, thereby locking the swivel head 38 in position in the plane 18.2.

5 The accessory 66 is then removed and a longer pin (not illustrated) inserted into the guide tube 48 until its tip touches the setting diagram. The pin is now manoeuvred, thereby swivelling the guide 46, until the tip of the pin is in register with the point D on
10 the setting diagram. The clamping screws 44 are then tightened, thereby locking the guide 46 in position with respect to the swivel head 38.

From the co-ordinates obtained in the CT scan it is also possible to determine the distance between
15 the upper end of the guide tube 48 and the target. This distance can be computed by the computer and printed on the setting diagram 64.

The guidance device 10 is now ready for use by the surgeon and is sterilized before going into the
20 operating theatre.

If desired, the setting of the guidance device 10 can be verified by making use of a phantom such as the one designated 80 in Figure 8. The phantom 80 comprises a flat plate 82 which has an opening 84 therein and is supported on a bottom plate 86 via legs 88. Spaced around the opening 84 there are three small pits 90 in parts of the plate 82 that project into the opening 84, for locating the feet 16.1 to 16.3 of the guidance device 10. The phantom 80 further comprises a
25 block 92 with a mark 94 thereon, the mark 94 representing the target. The block 92 is slidable along a bar 96. The bar 96 is fixed to a block 98 which is in turn slidable along a bar 100, and the bar
30

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100 is fixed to a block 102 which is in turn slidable along one of the legs 88. The bars 96 and 100, and the leg 88 in question are at right angles to one another and are each marked with graduations. The blocks 92, 5 98, and 102 are also each provided with a clamping screw (not shown) whereby they can be locked into any desired position along the corresponding bar or leg. This enables the target block 92 to be adjusted to a position in which the co-ordinates of the target 94 10 relative to the positions of the pits 90 correspond to those of the target in the patient's brain relative to the centres of the marker discs 62.1 to 62.3.

To verify the setting of the guidance device 10, a long pin (not shown) with a displaceable collar 15 thereon is set up so that the distance between the tip of the pin and the collar corresponds to the computed distance from the upper end of the guide tube 48 to the target. The guidance device 10 is placed on the phantom 80, with each of the feet 16.1 to 16.3 seating 20 in the corresponding pit 90, and the long pin with the collar thereon is inserted into the guide tube 48 until the collar abuts on the upper end of the guide tube. The tip of the pin should now be in register with the target 94. In this manner the surgeon will be able to 25 satisfy himself that the setting of the guidance device is correct.

The phantom 80 can be of stainless steel construction, so that it can be sterilized for use in the operating theatre.

30 When the patient is ready for the surgical part of the biopsy procedure to commence, the surgeon will mark the positions of the marker discs 62.1 to 62.3 on the patient's skin with an indelible marking fluid. This can be done through the openings left by

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the removal of the steel balls referred to earlier. The marker discs are then removed. If desired, stainless steel marker pins having pits therein for locating the feet of the guidance device 10 may be 5 placed on each of the marks and secured in position by driving them into the bone of the patient's skull, so as to fix them with respect to the skull.

The surgeon now enters the patient's cranium at the mark that marks the entry point. Once the 10 patient's cranium has been entered, a biopsy needle is inserted through the guide tube 48 into the patient's brain. The biopsy needle is provided with an adjustable collar which is clamped in position at a point corresponding to the distance to which it is to 15 be inserted to reach the target. Thus, when the collar abuts on the upper end of the guide tube 48, the surgeon will know that the tip of needle is at the position of the target, whereupon a biopsy can be taken and the biopsy needle withdrawn.

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CLAIMS

1. A surgical guidance device for the precise positioning of a surgical object, characterised in that it comprises:

a base (12) having three feet (16.1...16.3) which define a first plane (18.1);

a swivel head (38) which is constrained for movement in a second plane (18.2) spaced from and parallel to the first plane (18.1);

a guide (46) for the surgical object, the guide being mounted on the swivel head (38) so that it can swivel with respect to the swivel head in all directions about a pivot point; and

locking means (34, 44) for locking the swivel head (38) in a selected translational position in the second plane (18.2) and the guide (46) in a selected angular position with respect to the swivel head.

2. A surgical guidance device as claimed in claim 1, characterised in that the swivel head (38) is mounted on a radius arm (30), the radius arm being mounted on the base (12) so as to be pivotally displaceable with respect to the base about a pivot axis (24) normal to the first plane (18.1), and the radius arm (30) being slidably displaceable with respect to the base (12) or the swivel head (38), whereby the radial distance between the swivel head (38) and pivot axis (24) can be varied.

3. A surgical guidance device as claimed in claim 1 or claim 2, characterised in that the guide (46) comprises a guide tube (48) along which a pin forming the surgical object or having the surgical object attached thereto, can slide with little clearance, the tube (48) being connected to the swivel head (38) via a ball-and-socket connection (40, 42, 50).

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4. A surgical guidance device as claimed in claim 3, characterised in that the guide tube (48) has a spherical formation (50) between the ends and on the outside thereof, and in that the swivel head comprises a pair of annular clamping plates (40, 42) between which the spherical formation is held, the clamping plates and the spherical formation forming said ball-and-socket connection, and locking of the guide in a selected angular position with respect to the swivel head being effected by clamping the clamping plates together to grip the spherical formation therebetween.

5. A surgical guidance device as claimed in any one of the preceding claims and, in combination therewith as part of a kit, a phantom (80) which comprises a plate (82) having an opening (84) therein and, spaced around the opening, three locating formations (90) whose positions relative to one another correspond to the positions of said feet (16.1...16.3) relative to one another, and the phantom further comprising a target block (92) below the opening (84), the target block (92) being slidable in three mutually orthogonal directions along graduated slides (96, 100, 88).

6. A method of guiding a surgical object to a target position in a patient, characterised in that it comprises:

utilising a guidance device (10) having a base (12) with three feet (16.1...16.3) which define a first plane (18.1), a swivel head (38) which is constrained for movement in a second plane (18.2) spaced from and parallel to the first plane (18.1), and a guide (46) for the surgical object, the guide (46) being mounted on the swivel head (38) so that it can swivel with respect to the swivel head in all directions about a pivot point;

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applying at least three markers (62.1...62.3) to the body of the patient, the positions of the markers relative to one another corresponding to the positions of said feet (16.1...16.3) relative to one another;

determining the co-ordinates of the target position and each of the markers (62.1...62.3), in a three co-ordinate system;

setting up the guidance device (10) by adjusting the translational position of the swivel head (38) in the second plane (18.2) and adjusting the angular position of the guide (46) with respect to the swivel head (38);

locking the swivel head (38) and the guide (46) in their adjusted positions;

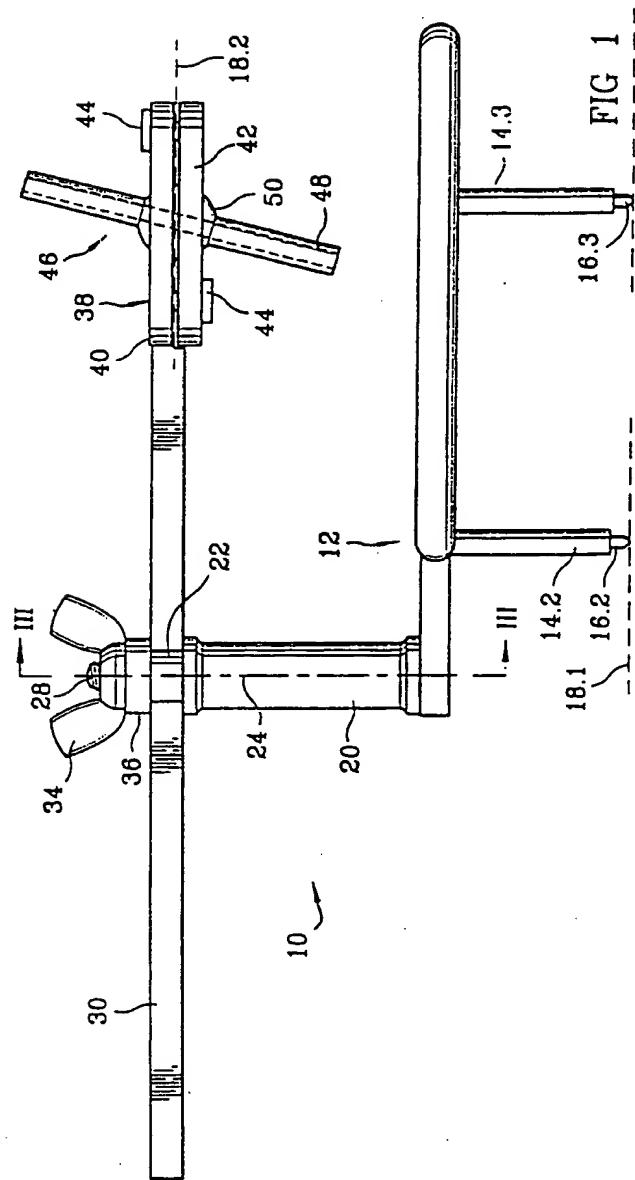
placing the guidance device (10) on the patient so that the feet (16.1...16.3) are in register with the positions of said markers (62.1...62.3); and

inserting the surgical object into the patient along the guide (46).

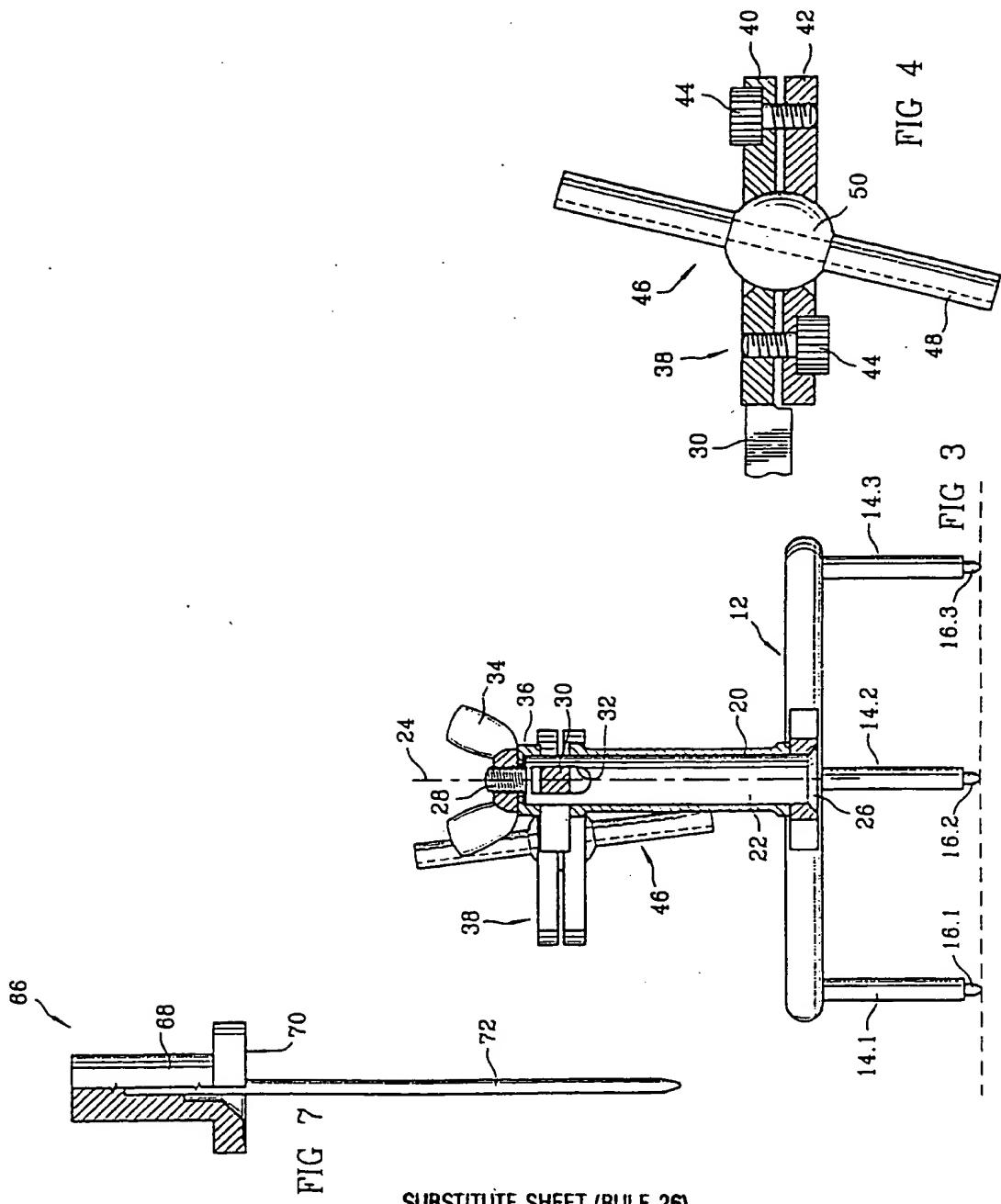
7. A surgical guidance device substantially as herein described and illustrated.

8. A method of guiding a surgical object precisely to a target position in a patient, substantially as herein described and illustrated.

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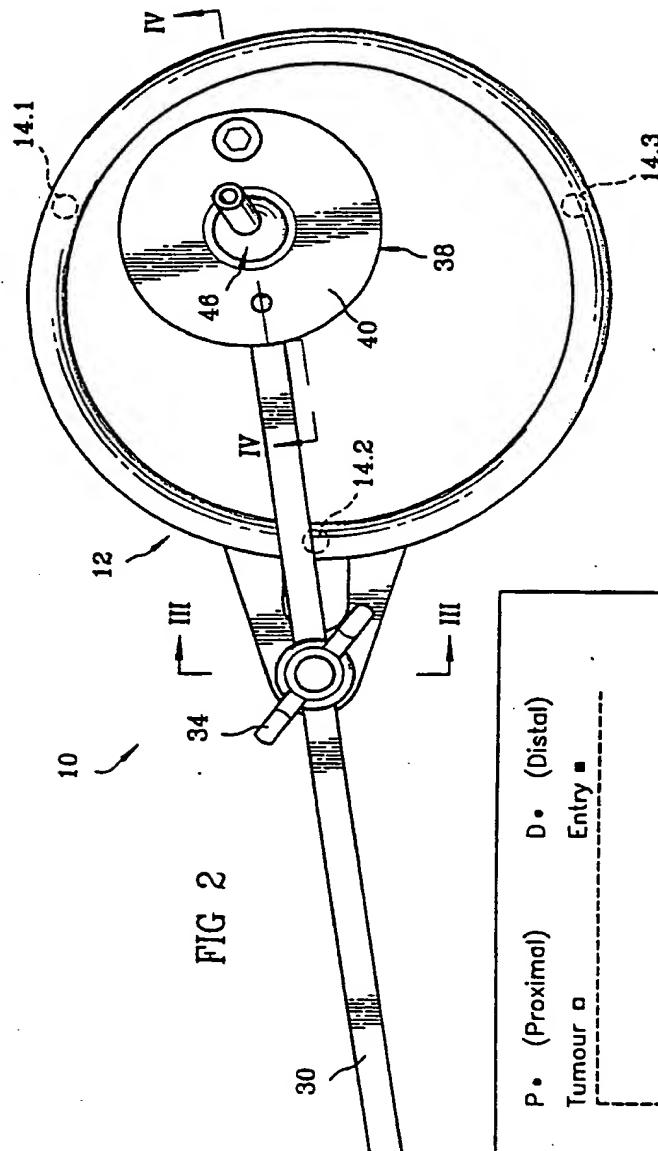


FIG 2

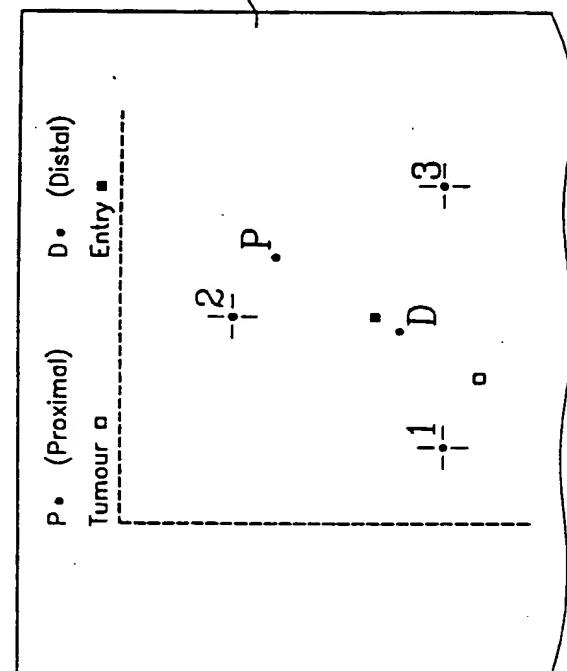
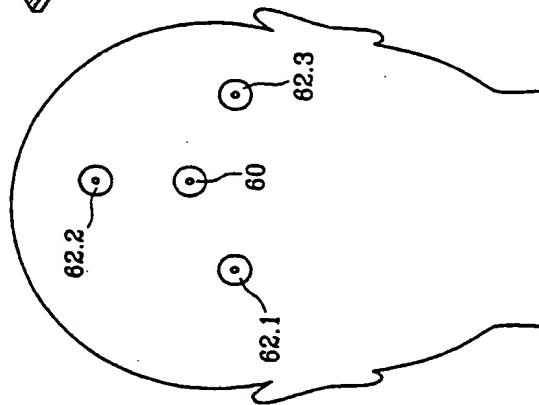
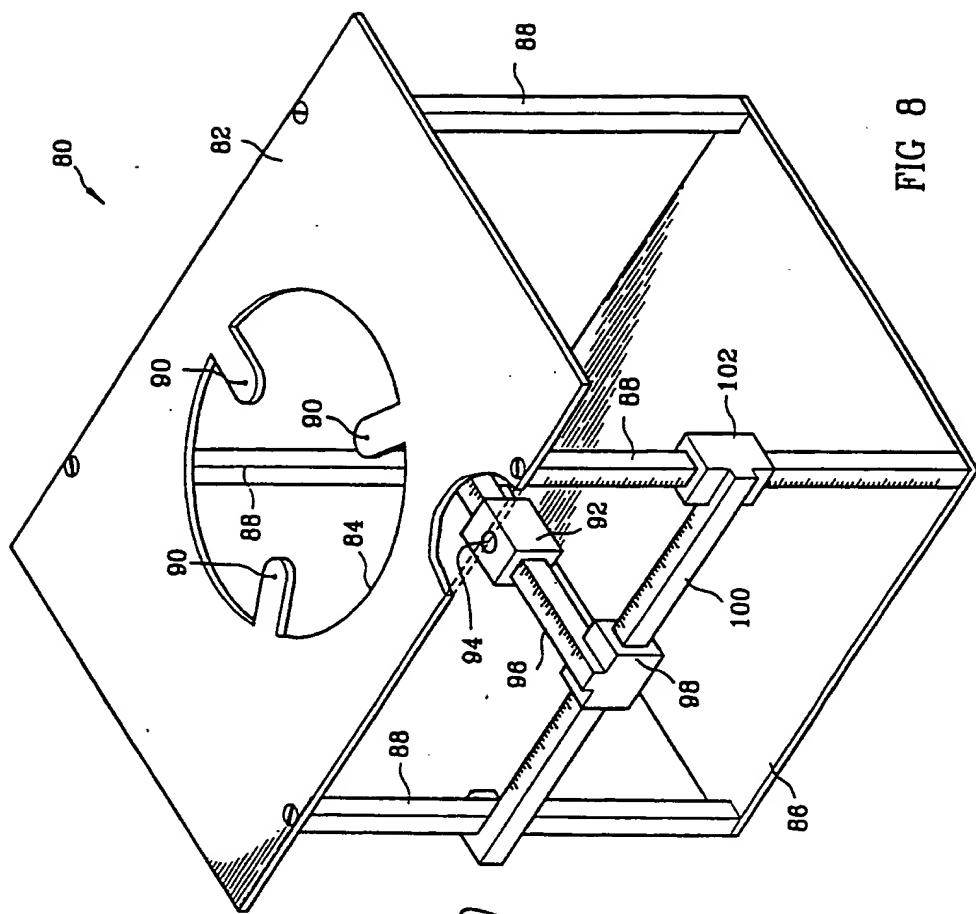


FIG 6



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INTERNATIONAL SEARCH REPORT

International Application No
PCT/NL 95/00063

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B19/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US,A,3 457 922 (C. D. RAY) 29 July 1969 see column 2, line 68 - column 4, line 20	1-4,7
Y	---	5
X	US,A,3 073 310 (Z. R. MOCARSKI) 15 January 1963 see column 3, line 12 - column 4, line 40	1,2,7
Y	EP,A,0 207 452 (M. P. MARK) 7 January 1987 see page 16, line 19 - page 21, line 21; figures 4,5,13	5

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- 'A' document defining the general state of the art which is not considered to be of particular relevance
- 'E' earlier document but published on or after the international filing date
- 'L' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- 'O' document referring to an oral disclosure, use, exhibition or other means
- 'P' document published prior to the international filing date but later than the priority date claimed

- 'T' later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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Date of the actual completion of the international search

10 May 1995

Date of mailing of the international search report

24.05.95

Name and mailing address of the ISA

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/NL95/00063

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: **Claims 6, 8**
because they relate to subject matter not required to be searched by this Authority, namely:
Method for treatm. of the human body by surgery Rule 39.(iv) PCT

2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internat.	Application No
	PCT/NL 95/00063

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-3457922	29-07-69	NONE	
US-A-3073310	15-01-63	NONE	
EP-A-207452	07-01-87	US-A- 4805615 AU-A- 5948786 CA-A- 1278969 JP-A- 62038147 US-A- 4955891	21-02-89 08-01-87 15-01-91 19-02-87 11-09-90